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10/089,696	07/24/2002	Yukoh Hiei	0760-0304P	5503

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EXAMINER	
HWU, JUNE	

ART UNIT	PAPER NUMBER
1661	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/089,696	HIEI ET AL.	
	Examiner	Art Unit	
	JUNE HWU	1661	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 November 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9,12,15,18 and 21-30* is/are pending in the application.

4a) Of the above claim(s) *9,12,15,18 and 21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22-30* is/are rejected.

7)☐ Claim(s) *22, 27 and 30* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendment and declaration filed on November 13, 2007 have been acknowledged and entered.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 13, 2007 has been entered.

Status of the Claims

Claims 1-8, 10-11, 13-14, 16-17, 19-20 are cancelled; claims 12, 15, 18 and 21 are withdrawn; claims 22-30 will be examined on the merits.

Objections to the Claims

Claims 22, 27 and 30 objected to because of the following informalities:

Claims 22, line 6; 27, line1; and 30, line 7 are missing a comma before "wherein".

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 30 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 30 is unclear in its recitation of "maize angiosperm." It uncertain what is meant by the phrase "maize angiosperm." Are all angiosperm included with the maize or only maize?

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 22-29 remain rejected and claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Konzak et al (U.S. Patent No. 6,362,393) in view of Forreiter et al (The Plant Cell, 1997, vol. 9, pp. 2171-2181) and in light of Pierce Biotechnology, Inc., 1/2005 Convert between times gravity (x *g*) and centrifuge rotor speed (RPM). The rejection is modified from the rejection set forth in the Office action mailed January 10, 2007, due to Applicant's amendment of the claims.

The claims are drawn to a method of plant transformation comprising centrifuging the plant, plant cell, or plant tissue of rice or maize (plants from the family *Gramineae*, a monocot and an angiosperm) at an acceleration of 1000G to 150,000G, and contacting the plant, plant

cell or plant tissue with *Agrobacterium* wherein the centrifugation occurs between 1 second to 4 hours, to plant cells or plant tissue, before gene transfer utilizing.

Konzak et al teach a method of centrifuging plant tissues (col. 4, lines 6-9) of rice or corn (col. 6, lines 29-32) at the acceleration of 100G for 3 minutes (col. 16, line 1) prior to gene introduction. Moreover, Konzak et al taught that gene transformation could occur at any time of the procedure (col. 4, lines 30-36) by using *Agrobacterium tumifaciens* (col. 12, lines 53-56).

Konzak et al reference does not teach the centrifugation speed of 1000G to 150,000G.

Forreiter et al. teach a method of gene transfer *Arabidopsis thaliana*, an Angiosperm; protoplasts were collected by 10 minutes of centrifugation at 600G. Then transient transformation was performed (page 2179, 1st paragraph).

It would have been obvious to one of ordinary skill in the art to use the method of promoting gene introduction into plant cells by centrifuging the plant cells or plant tissues before gene introduction by applying *Agrobacterium* as taught by Konzak et al, and to modify that method by adjusting the centrifugal acceleration as taught by Forreiter et al given the advantage of separating the tissues at higher speed. One would have been motivated to do so, given the effectiveness of separating plant tissue cells by centrifugation. The rate and time of the centrifugation is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for a skilled artisan to determine the optimal rate and time in order to best achieve the desired results. It is noted that Pierce Biotechnology discloses "centrifugation speed and time often are not critical factors in routine sampling-handling… as long as speed and time are sufficient to ensure that cells, debris or resin are pelleted effectively, it does not matter if the speed is faster or the time longer than necessary" (p. 1, 3rd paragraph). Thus, absent some demonstration of unexpected

results from the claimed parameters, this optimization of rate and time of centrifugation would have been obvious at the time of Applicants' invention.

Thus, the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Applicants' arguments filed November 13, 2007 have been fully considered but they are not persuasive.

Applicants urge that the procedure for centrifugation as taught by Konzak et al would have lead a skilled artisan to be able to transform cells more efficiently by slow centrifugation speed (p. 9 of reply).

This argument is not found persuasive because Konzak et al was combined with Forreiter et al who taught that *Arabidopsis* cells were centrifuged for one minute at 600 g (p. 2178). Moreover, Pierce Biotechnology as stated above that "speed and time are not critical factors" as long as the cells are pelleted effectively. Thus, the centrifuged speed is unimportant. These different x *g* rates are within the parameters of what one of skill in the art would routinely use to pellet cells. The instant claims do not exclude pelleting to separate from plant debris. In addition, Applicants appear to attacking the references individually. One cannot show non-obviousness by attacking references individually where the rejections are based on combinations of references.

Applicants urge that Konzak et al teach a method of purifying microspores of wheat by centrifuging the microspores from plant debris and other cell organelles (p. 9 of reply).

This argument is not found persuasive because by purifying the microspores by centrifugation, the microspores would be denser and suitable for transformation. Konzak et al

stated that their method of producing plants may optionally include the step of genetic transformation (col. 4, lines 31-36).

Applicants urge that Konzak et al may include an optional transformation but is performed after the microspore is isolated by the preparative centrifugation step (p. 9 of reply).

This argument is not found persuasive because the instant claims also state that the transformation occurs after centrifugation (see claim 22, lines 4-7 and claim 30, lines 5-9).

Applicants urge that the statement "Microspores can be genetically transformed at any time during treatment of the microspores… (col. 4, lines 33-36)" by Konzak et al would be construed as a preparative step and that the centrifugation and gene transfer are separate events and are completely independent from each other (p. 9 of reply).

This argument is not found persuasive because as stated above the instant claims recite a procedure for centrifuging plant cell, plant or plant tissue and then contacting the plant cell, plant or plant tissue with the desired gene. These steps are two separate events.

Applicants urge that Forreiter et al method of centrifuging *Arabidopsis* cells is preparative in nature and is independent to the transformation method (pp. 9-10 of reply).

This argument is not found persuasive because as stated above the instant claims recite two separate and independent steps for transforming plant, plant cell or plant tissue.

Applicants urge that Forreiter et al do not motivate a skilled artisan to contemplate a high *g* centrifugation because the transformation efficiency would be assessed during the transformation event itself (p. 10 of reply).

This argument is not found persuasive because Forreiter et al was combined with Konzak et al to show that centrifugation may be used with the method of Konzak et al of centrifuging the microspores and then transforming the microspores. The different x *g* rates are

within what one of skill in the art would routinely use to pellet cells. The instant claims do not exclude pelleting to separate from plant debris.

Applicants urge neither Konzak et al or Forreiter et al alone or in combination teach or suggest that "centrifuging the plant, plant cells or plant tissues under a centrifugal acceleration of 1000G to 150,000G…centrifugation promotes efficiency of the transformation" (p. 10 of reply).

This argument is not found persuasive because in common lab practice, cells are centrifuged at a given rpm, regardless of rotor size, and thus regardless of x *g*. Pierce shows that a small change in rotor size would change a given x *g* to another, for example, at 3000 rpm changing from a rotor radius of 6 cm to one of 10 cm would change the x *g* from 604G to 1006G. So, the use of a different rotor size would change the x *g*. Moreover, efficiency would be increased because the cells would be separate from other materials and from liquid media, etc.

Applicants urge that Konzak et al and Forreiter et al teach away from the instant invention because a skilled artisan would utilized the centrifugation methods within each as a preparative step mainly to isolate a material from a mixture (p. 10 of reply).

This argument is not found persuasive because the instant claims appears to be isolating the plant, plant cells or plant tissues by centrifugation and then contacting the plant, plant cells or plant tissues to *Agrobacterium*.

Applicants urge that a skilled artisan would not use the method taught by Konzak et al because Konzak et al involve a sugar density gradient centrifugation to separate plant organelles and would not make the link with the cell culture and time to assess transformation efficiency as taught by Forreiter et al (pp. 10-11 of reply).

This argument is not found persuasive because as stated above Konzak et al taught a method of centrifuging microspores and optionally utilizing transformation for creating a new plant and then using the method of high *g* centrifugation as taught by Forreiter et al for stable transformation of *Arabidopsis*.

Applicants urge that the increased centrifugal acceleration between 1000G and 150,000G is an unexpected result and that a skilled artisan would not have expected transformation efficiency (p. 11 of reply).

This argument is not found persuasive the differences in transformation efficiency in Tables 1-3 between samples centrifuged at <1000G and those centrifuged at >1000G is often not significant or even decreased (see Table 1, last line specifically between 750G and 8,500G). Tables 1-3 do not show consistent results, wherein there are significant differences between sampled centrifugal accelerations. For example, Table 2, line 1 shows some difference between 760G and 19,100G on the other hand at line 4 there is no difference between 760G, 8,500G and 19,100G.

Applicants urge that neither Konzak et al nor Forreiter et al describe or suggest a relation between centrifugation and gene transfer (pp. 11-12 of reply).

This argument is not found persuasive because Konzak et al and Forreiter et al were combined to show the centrifugation and transformation would have been obvious to one of ordinary skilled in the art because centrifugation of plant cells as taught by Forreiter et al would have separated the cells and then it would have been obvious to use the method of transformation to create a new plant as taught by Konzak et al.

Applicants urge that the relation between centrifugation acceleration and rotor size does not make sense with regard to centrifugation and gene transfer efficiency (p. 12 of reply).

This argument is not found persuasive because the Pierce reference was to show that centrifugal force is dependent on rotor size.

Applicants urge that gene transfer efficiency is improved by centrifugation speed (p. 12 and Hiel declaration).

This argument is not found persuasive because the centrifugation speed of 600G as taught by Forreiter et al is within the parameter of 1000G as claimed because it would be dependent of the rotor radius. For example, Pierce reference discloses a rotor radius of 6 cm would have the same centrifugal force if the rotor radius of 10 cm. Thus, centrifugation speed is dependent of rotor size. Hiel declaration states that there is a difference between no centrifugation and 760 xg, 1000 xg and 2000xg on GUS activity. Table 1 of Hiel declaration shows very little GUS activity between 760 xg and no centrifugation. However, 1000 xg and 2000 xg did show GUS activity for rice varieties. Instant claim 22 is to any plants.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to June Hwu whose telephone number is (571) 272-0977. The Examiner can normally be reached Monday through Thursday from 6:00 a.m. to 4:30 p.m.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Anne Marie Grunberg, can be reached on (571) 272-0975. The fax number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JH

/Anne R. Kubelik/
Primary Examiner, Art Unit 1638